**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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| **IN RE SUBOXONE (BUPRENORPHINE HYDROCHLORIDE AND NALOXONE) ANTITRUST LITIGATION** | **MDL NO. 2445**<br>**13-MD-2445** |
| **THIS DOCUMENT RELATES TO:,**<br>*Wisconsin, et al. v. Indivior Inc. et al.*<br>Case No. 16-cv-5073 | |
| **STATE OF WISCONSIN**<br>**By Attorney General Brad D. Schimel, *et al.***<br>**Plaintiffs,**<br>**v.**<br>**INDIVIOR INC. f/k/a RECKITT BENCKISER PHARMACEUTICALS, INC., et al.**<br>**Defendants.** | **CIV. A. NO. 16-5073** |

**MEMORANDUM OPINION**

**Goldberg, J.** **October 19, 2022**

This multidistrict litigation case involves an alleged "product hop" antitrust scheme wherein the patent holder allegedly sought to maintain market exclusivity by changing the formulation of its product.

Defendant Reckitt Benckiser, Inc. ("Reckitt") manufactures Suboxone, a drug commonly used to combat opioid addiction.[1] Suboxone previously came in tablet form, but in 2010, citing

[1] Reckitt is currently known as Indivior, Inc. In December 2014, Reckitt Benckiser Pharmaceuticals, Inc. was demerged from its prior parent, the Reckitt Benckiser Group PLC, into Indivior PLC. Although Indivior is technically the named defendant in this case, the pleadings and many of the relevant exhibits use the name "Reckitt." To avoid confusion, I will refer to Indivior as Reckitt.

safety concerns, Reckitt effectuated a change in the administration of this drug, switching from a tablet to a sublingual film. MonoSol Rx LLC ("MonoSol") designed and manufactured this film pursuant to contracts with Reckitt.[2] Plaintiffs allege that Reckitt then conducted a marketing campaign designed to convert the market demand from tablets to film, falsely touting the safety benefits of film over the risks associated with tablets.[3] Plaintiffs claim that Reckitt also took several actions designed to delay the entry of generic Suboxone tablets including filing a baseless Citizen Petition with the Food and Drug Administration and delaying the progress of a required safety study shared with generic manufacturers. All Plaintiffs assert that this switch, and the associated conduct, were anticompetitive and solely designed to maintain Reckitt's market exclusivity. In recently denying Reckitt's motion for summary judgment, I found that the antitrust claims brought against Reckitt must be resolved by a factfinder.

Separately, a group of States' Attorneys General ("States") have also sued MonoSol in connection with these antitrust claims, alleging that MonoSol conspired with Reckitt both to restrain trade and to monopolize in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1 and to monopolize under Section 2 of the Sherman Act, 15 U.S.C. § 2. This Opinion addresses the Motion for Summary Judgment filed by MonoSol, who asserts that there is no genuine issue of material fact as to whether it entered into an antitrust conspiracy. For reasons explained in this Opinion, I agree with MonoSol's position and will grant MonoSol's Motion.

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[2] In December 2017, MonoSol Rx changed its name to Aquestive Therapeutics, Inc. For purposes of consistency with the bulk of the exhibits in this case, I will refer to Aquestive as MonoSol.

[3] Plaintiffs include a group of direct purchasers ("Direct Payor Plaintiffs" or "DPPs"), a group of ultimate consumers ("End Payor Plaintiffs" or "EPPs"), and a group of States' Attorneys General ("States"), (collectively, "Plaintiffs").

## I. FACTUAL AND PROCEDURAL BACKGROUND

A detailed recitation of the antitrust allegations has been set forth at length in my Opinion in In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litigation, No. 13-md-2445, 2022 WL 3588024 (E.D. Pa. Aug. 22, 2022), where I denied Reckitt's Motion for Summary Judgment. Id. at *2–12. In lieu of repeating that factual summary, I will focus solely on the facts pertinent to MonoSol's pending Motion for Summary Judgment. These facts are derived from the evidence submitted by the parties in support of and in opposition to summary judgment. Where there is conflicting evidence about a particular fact, Federal Rule of Civil Procedure 56 requires that I view all facts and evidence in the light most favorable to Plaintiffs. [4]

### A. MonoSol's Drug Delivery System

MonoSol specializes in the development of film drug delivery products. (DSUF ¶ 1; PR ¶ 1.) MonoSol developed a thin film (registered as PharmFilm®) similar in size, shape, and thickness to a postage stamp that dissolves rapidly and utilizes proprietary techniques to mask the taste of the drug contained in the film. (DSUF ¶ 2; PR ¶ 2.) MonoSol spent years developing a polymer composition, which is essentially a unique composition of molecules that holds in place the active pharmaceutical ingredients ("API") and the film's other, inactive ingredients. (DSUF ¶ 3; PR ¶ 3.)

MonoSol obtained hundreds of patents worldwide protecting the various aspects of its intellectual property, including the proprietary processes that it uses to ensure that the API is

[4] References to the parties' pleadings will be made as follows: Defendant MonoSol's Statement of Undisputed Facts ("DSUF"); Plaintiffs States' Response ("PR"), Plaintiffs' Additional Statement of Facts ("PASF"), and Defendant MonoSol's Response ("DR"). To the extent a statement is undisputed by the parties, I will cite only to the parties' submissions. If a statement is disputed and the dispute can be easily resolved by reference to the exhibits, I will cite the supporting exhibits. If a statement is disputed, but the dispute cannot be resolved by reference to the exhibits, I will note the dispute. I will not rely on any statement of fact that is unsupported by reference to a specific exhibit.

uniformly distributed throughout the film. (DSUF ¶ 4; PR ¶ 4.) MonoSol marketed that its film offered protection from generic competition because the film was not AB rated to other delivery forms such as pills and, therefore, extended the life of a patent. [5] (States' Ex. 1, Rule 30(b)(6) Dep. of A. Mark Schobel ("Schobel 30(b)(6) Dep.") 187:19–188:22, 254:19–22; States' Ex. 2.) From its inception, MonoSol believed that its film products offered benefits to patients, physicians, and pharmacists, as well as IP protection to its partner drug manufacturers. (DSUF ¶ 6; PR ¶ 6; States' Exs. 4 and 5.)

In June 2006, MonoSol spoke to regulatory consultant Robert Pollock of Lachman Consultant Services seeking regulatory advice and assistance in formulating a marketing strategy for its film product. MonoSol was informed that "[a] film strip could not be rated AB to a ODT [orally dissolving tablet] because by definition they are considered different dosage forms (even if they are shown to be bioequivalent.)." (States' Ex. 23.)

In late 2007, MonoSol conducted a study on the benefits of film, the results of which revealed that "[r]eactions to the Thin Film drug delivery form were overwhelmingly positive." (MonoSol Ex. 6.) The study showed several "[k]ey likes" including: quick dissolving, rapid onset/acts immediately/speed, bypasses GI, no need for water, easy to administer (particularly to children and elderly), no difficulty swallowing/no gagging, easy to carry/portable/light weight/good for travel, easy to find if dropped, convenience, discretion (especially on a plane), precise dosing/no chance of error, flavoring, and cleanliness/sanitary. (Id.) Medical expert Dr. Laurence Westreich testified that "some patients prefer [film] and some patients are just better treated with film than

[5] Oral drugs proven to be both bioequivalent and pharmaceutically equivalent—meaning the generic drug has the same active ingredient of the branded oral drug—receive an "AB" rating from the FDA. In most cases, only oral generic drugs with an AB rating may be substituted by pharmacists for a physician's prescription of a brand-name drug without the physician's approval. In most states, and under most health plans, a pharmacist may, and in many cases must, substitute an AB-rated generic drug for a prescribed brand-name drug.

with tablet." He noted that, in treating opioid use disorder, it is helpful to have a broad range of treatment options from which to select for individual patients. (MonoSol Ex. 5, Dep. of Laurence Westreich ("Westreich Dep."), 76:21–77:11, 80:19–81:5.)

**B. The Partnership Between Reckitt and MonoSol**

1. Early Talks

On October 8, 2002, the Food and Drug Administration ("FDA") approved Reckitt's drug Suboxone (buprenorphine naloxone) in the form of a tablet to treat opioid dependence (the "Suboxone tablet") and granted Reckitt seven years of orphan drug exclusivity, to expire October 8, 2009. (DSUF ¶ 9; PR ¶ 9.) In January 2006, Reckitt's Buprenorphine Business Group prepared a 2006 business development plan that included "[r]eplac[ing] existing product"—Suboxone tablets—with another dosage form such as film, buccal, transdermal gel, or sublingual spray. (DSUF ¶ 10; PR ¶ 10.) Reckitt never shared its 2006 business development plan with MonoSol. (DSUF ¶ 11; PR ¶ 11.)

MonoSol's Chief Executive Officer ("CEO") Mark Schobel, who joined MonoSol on December 15, 2005, recalled that, at that time, there had been many ongoing discussions with Reckitt. (MonoSol Ex. 1, Dep. of March Schobel ("Schobel Dep."), 68:17–69:2.) According to Schobel, Reckitt was seeking a company who could make a film version of Suboxone, had good intellectual property, and had the capabilities to develop a product. (Schobel Dep. 70:14–18.)

On April 27, 2006, MonoSol met with Reckitt to discuss buprenorphine products. (Schobel Dep. 78:28–69:2; Decl. of A. Mark Schobel ("Schobel Decl.") ¶ 12.) Mr. Schobel testified that MonoSol did not agree to partner with Reckitt to replace Suboxone tablets with film either at that April 27th meeting or at any other time. (Schobel Decl. ¶ 13; Schobel 30(b)(6) Dep. 421:17–422:6.)) MonoSol understood, in September 2006, that the goal for Suboxone film was to get it to market in advance of the expiration of the Suboxone tablets' exclusivity period. (PSUF ¶ 74; DR ¶ 74.)

On November 2, 2006, Mr. Schobel emailed Brian Bentley, a Reckitt executive, outlining several "strategic points" that Mr. Bentley "could use in the communication to [Reckitt's] CEO regarding [MonoSol's] technology and the [buprenorphine naloxone] film project":

> 1. Thin Film Drug Delivery outperforms every other oral dosage form (including ODT's) with respect to speed of disintegration, compliance, perceived onset of action, portability and purchase intent.
>
> 2. Thin Film Drug Delivery is a highly unique and new discipline that cannot be easily replicated. Drug delivery and the associated worldwide infrastructures/supply chains are all based on traditional dosage forms such as tablets, capsules, liquids and aerosols not films. Assuming a Company can avoid the patent minefield that exists, one **cannot** simply hire people with the requisite experience (as it does not exist), build a cGMP pharmaceutical film factory, engineer the right equipment and formulate robst/scaleable film products within a 2–3 year period.
>
> 3. Your sNDA for thin film buprenorphine/naloxone, once approved, will become the RLD that all other prospective thin film competitors will have to use for BE studies and subsequent ANDA's. This gives Reckitt-Benckiser at least a 36–42 month head start on the competition post-launch apart from the significant buffering that our IP and know-how offers in this technological field.
>
> 4. Your thin film product once prescribed by a physician will **not** be AB rated and thus cannot be generically substituted by the Pharmacist with a tablet or any other non-film dosage form delivering the same actives.
>
> 5. If you were to add up the head start in terms of timing it is easily at least 6+ years post-launch and this does not include the 20 year firewall that our IP will provide.

(MonoSol, Ex. 9 (emphasis in original).)

At the time, no prescription for Suboxone in a film dosage form was on the market, nor had the dosage form been presented to the FDA for approval. (DSUF ¶ 16; PR ¶ 16.) Reckitt wrote to MonoSol, on November 15, 2006, that it was "excited by the potential the development has regarding the level of IP protection and managed care benefit." (States' Ex. 25.)

2. The Development Agreement

On December 11, 2006, MonoSol executed a "Development Agreement for a Pharmaceutical Film" (the "Development Agreement"). (DSUF ¶ 17; PR ¶ 17.) The Agreement provided that MonoSol would develop and test a film dose form product containing the active ingredients in Suboxone. MonoSol was also required to cooperate with Reckitt Benckiser Healthcare (UK) Limited regarding any arising intellectual property rights. (MonoSol Ex. 10, § 4 & Schedule 1; PSUF ¶ 77; DR ¶ 77.) Nothing in the Development Agreement imposed any marketing or pricing responsibilities on MonoSol with respect to Suboxone film. (Id.)

On December 15, 2006, MonoSol's regulatory consultant, Mr. Pollock, attended a meeting between MonoSol and Reckitt. (PSUF ¶ 78; DR ¶ 78.) According to Reckitt's characterization, the reason for this meeting was to understand "the possible protection a MonoSol product could provide vs generic particularly in regard to pharmacist substitution and managed care payment." (States' Ex. 28.) In communications with Mr. Schobel of MonoSol, Reckitt enumerated three goals of the meeting: "1. Product development success probability with details[;] 2. A US clinical program and regulatory submission details and timelines[; and] 3. Orange book A/B rating assumptions of substitutability with analogs." (States' Ex. 27.) Although Reckitt's understanding from the meeting was that "the rationale is 100% replacement and withdraw Suboxone NDA [New Drug Application to the FDA] thus preventing a generic," Mr. Schobel testified that the possibility of Reckitt withdrawing the tablet from the market never came up at any point in that meeting. [6] (States' Ex. 8; MonoSol Ex. 28, Schobel Dep. 236:17–237:1.)

[6] Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–92 ("FDC Act"), a manufacturer who creates a new drug must obtain the approval of the Food and Drug Administration ("FDA") to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and efficacy of the drug, as well as any information on applicable patents.

On January 23, 2007, Reckitt executive Andy Newhall identified two key issues to be addressed with regard to the agreement with MonoSol: (1) "[d]oes this provide some defence against Generic. Here we need to have external regulatory opinion that Monosol[']s proposed route provides this defense" and (2) "[w]hat would be the barriers to removing sublingual tablets off the market and replacing them with Monosol product. Here patient acceptance of the format is key and we need to ascertain this." (States' Ex. 8.) In February 2007, Reckitt engaged PharmaDirections as the external regulatory consultant for "urgent evaluation" of proposed development plans with MonoSol and review of the regulatory strategy proposed by Lachman Consulting, MonoSol's regulatory consultant. (States' Ex. 9.) PharmaDirections characterized MonoSol's regulatory strategy as "replac[ing] the current sublingual tablet product with an ODF [film] formulation and then withdraw[ing] the tablet from the market." (States' Ex. 10.)

On February 22, 2007, several individuals from Reckitt, including Tony Goodman, Reckitt's Director of Business Development, joined representatives of MonoSol for a conference call. MonoSol's regulatory consultant, Robert Pollock, was also on the call. (DSUF ¶¶ 20–21; PR ¶¶ 20-21.) During that call, Mr. Pollock took some handwritten notes, including "WDSL tab to delay," which meant "withdraw sublingual tablet to delay." (DSUF ¶¶ 22–23; PR ¶¶ 22–3.) Mr. Pollock did not recall whether he or somebody else made that statement, what might be delayed, whether the issue of withdrawal came up, or whether generic drugs were discussed. (DSUF ¶ 24; PR ¶ 24.)

On February 22, 2007, Reckitt had an internal discussion regarding regulatory issues related to Suboxone film. (DSUF ¶ 27; PR ¶ 27.) Reckitt executive, Brian Bentley, asked, "if we withdraw the NDAs we have on the present products [Suboxone Tablets] does this prevent a Generic Referencing them." (DSUF ¶ 28; PR ¶ 28.) Tony Goodman responded, "Suboxone/Subutex Monosol formulation under the current path provides no generic protection. The NDA for Suboxone cannot be pulled as the generic will still have the right of reference to the data in the NDA." (DSUF

¶ 29; PR ¶ 29.) Reckitt understood that to obtain generic protection, it would have to remove tablets from the market by showing the safety benefits of the film over tablet in order to justify the withdrawal, and that this would have to be done prior to 2009, when the generics were projected to enter the market. (States' Ex. 11.) Mr. Goodman further noted that "[f]ormulation changes would need to show (and be proved) that Suboxone [M]onosol is less abuseable/divertible, hence the ability to pull the NDA. We believe it is worth pursuing this with Monosol, however, it will not be a formulation ready for clinic to meet 2009 launch." (Monosol Ex. 13.)

In February 2007, Reckitt's regulatory consultant, PharmaDirections, understood that "[t]he key consideration is to lifecycle management of the product and [Reckitt] is exploring ways to replace the old formulation (sublingual tablet) with the MonoSol Rx formulation. But they are having some issues with how best to achieve this." (States' Ex. 9.) PharmaDirections remarked that "[b]ased on [what] MonoSol's regulatory consultant has said, that if the formulation were bioequivalent you could (1) choose to keep the current products on the market or (2) withdraw the existing product and replace with new product but there is no assurance that they are substitutable." (States' Ex. 9.)

An internal Reckitt email, dated March 7, 2007, on the subject "Monosol RX Brainstorm – Meeting Recap," Reckitt's plan "call[ed] for introducing the film in June 2009, transitioning pts from the SL tabs to the film, and then withdrawing the SL tabs altogether prior to October, 2009." (States' Ex. 12.)

MonoSol and Reckitt met together more than once with the FDA, including in July 2007, regarding the development of Suboxone film. (PSUF ¶ 92; DR ¶ 89.) MonoSol applied for a pharmaceutical film technology patent in April 2008, which was granted in September 2011. (States' Ex. 29.) Once MonoSol had the patent (the 8017150 patent), Reckitt could reference it in its New Drug Application ("NDA") for Suboxone film. (PSUF ¶ 89; DR ¶ 89.)

3. The Commercial Exploitation ("Supply") Agreement

On August 15, 2008, Reckitt and MonoSol entered into a supply agreement, which they referred to as the "Commercial Exploitation Agreement." (the "Supply Agreement"). (DSUF ¶ 30; PR ¶ 30.) The Supply Agreement stated that "Reckitt wishes to engage [MonoSol] to manufacture and supply [Suboxone Film] on the terms of this Agreement and [MonoSol] wishes to manufacture and supply [Suboxone Film] to Reckitt on the terms of this Agreement." (DSUF ¶ 31; PR ¶ 31.) Reckitt was to provide periodic forecasts of expected film volume and MonoSol was required to meet the manufacturing demands. (MonoSol Ex. 14.) MonoSol represented and warranted it would have the capacity to fill Reckitt's requirements for the products so long as the amount specified in the order did not exceed 125% of the forecasted volume for such period as set forth in the previous forecast. (MonoSol Ex. 14 § 6.3.) In the event it could not fill Reckitt's requirements, Reckitt had the right to retain a temporary alternative supplier. (Id.) Mark Schobel, then MonoSol's president and CEO, signed the Supply Agreement on behalf of MonoSol. (DSUF ¶ 34; PR ¶ 34.)

Under the original terms of the Supply Agreement, Reckitt was to pay MonoSol a per strip price and royalty. (MonoSol Ex. 14 §§ 7.3, 7.4.) This royalty was a way for Reckitt to have MonoSol take a marketing risk. (States' Ex. 34, Kendall Dep. 27:5–10.) The royalty had an annual cap, and the Supply Agreement included an option for Reckitt to buy out the royalties altogether. (MonoSol Ex. 14, §§ 7.4, 7.7.) Under later terms of the Supply Agreement, Reckitt was required to buy out the royalties altogether, meaning that MonoSol received no additional royalties. (MonoSol Ex. 21, §§ 7.4.1, 7.18.)

One of the provisions of the Supply Agreement stated that, if Reckitt had to purchase the product from an alternative supplier, MonoSol agreed to (1) "grant [Reckitt] and the alternative supplier a limited, personal, non-exclusive royalty-free licence [sic], without the right to sublicense, to use [MonoSol's] applicable Intellectual Property Rights for such period as may be necessary for

the alternative supplier to be able to supply Products pursuant to the Forecasts"; and (2) use commercially reasonable efforts to promptly transfer such [MonoSol] Intellectual Property Rights . . ." (MonoSol Ex. 33, § 6.5.) As Mr. Schobel explained, this effectively meant that if MonoSol could not provide the supply then, it had to provide technology to a third-party provider, teach them how to make film, and let them access MonoSol's intellectual property so that they could supply the product for Reckitt. (DSUF ¶ 35; PR ¶ 35.)

MonoSol was cognizant of its limited manufacturing capacity. (Schobel Decl. ¶ 15.) MonoSol had the capacity to produce 170 m strips (non-Reckitt products) in 2007, budgeted for 350 m in 2008, and was building capacity for 3 billion for 2008 with a second facility. (States' Ex. 13.) In October 2008, Reckitt's initial volume estimate for Suboxone Film forecasted 2.8 million Suboxone film strips for 2009 and 30.6 million for the entirety of 2010. (MonoSol Ex. 16.) Mr. Schobel asserted that "[a]t MonoSol, we believed that Suboxone Film would always be available to patients along with tablets, so we thought our limited capacity to manufacture Suboxone Film was sufficient . . . [w]e would not have staked control of our intellectual property on our known capacity limits had we contemplated being asked to manufacture Suboxone Film for all buprenorphine/naloxone patients." (Schobel Decl. ¶¶ 16–17.)

The week after the Supply Agreement was signed, Mr. Schobel emailed Mr. Pollock for regulatory advice, asking "[i]f our customer, Reckitt-Benckiser, withdraws their sublingual Suboxone tablets from the market and changes the code for the Suboxone tablets in the NDDF [National Drug Data File] to 'obsolete' can pharmacies still fill prescriptions for a generic sublingual tablet?" (DSUF ¶ 39; PR ¶ 39.) Mr. Schobel testified that his concern was that if MonoSol was unable to provide the levels of volume requested by Reckitt, MonoSol would have to give away some of their intellectual property and train a competitor company to make the product. (DSUF ¶ 40; PR ¶ 40.) The States point out that MonoSol's intention, at least as of February 2007, was to

supply enough film to replace Reckitt's Suboxone tablet market. (States' Ex. 10 ("The approach recommended by MonoSol Rx is to replace the current sublingual tablet product with an ODF formulation and then withdraw the tablet product from the market. This would prevent generic companies from achieving an AB-rated product using the sublingual tablet as the reference listed drug (RLD).")

Mr. Pollack responded to Mr. Schobel that "if the SL [sublingual] tablet has not been withdrawn for safety or efficacy reasons, Generics can be approved for the SL product (it will not be AB rated since it is a pharmaceutical alternative." (DSUF ¶ 42; PR ¶ 42; MonoSol Ex. 4, Pollock Dep., 74:25–75:5.) According to Mr. Schobel, MonoSol was counting on generic entry of tablets so that MonoSol would be able to meet Reckitt's demand for film. (MonoSol, Ex. 1, Schobel Dep. 172:6–7, 174:19–20.)

MonoSol repeatedly requested information from Reckitt about the pricing that Reckitt set for Suboxone film so that MonoSol could determine what to charge Reckitt and to forecast its own royalties. (PSUF ¶ 99; DR ¶ 99.) MonoSol had a difficult time getting this information. (States' Ex. 34, Kendall Dep. 38:5–12.)

As noted above, in October 2008, Reckitt shared an initial volume estimate for Suboxone Film with MonoSol, reflecting an assumed demand for film of 2.8 million strips in the fourth quarter of 2009 and 30.6 million strips for the entirety of 2010. (MonoSol, Ex. 16.) These volume projections were excerpted from a more detailed model—not shared with MonoSol—which also contained Reckitt's volume projections for its Suboxone tablet. (DSUF ¶ 47; PR ¶ 47.) The Suboxone tablet projections expected 20.4 million Suboxone tablets for the fourth quarter of 2009, followed by 39.8 million in 2010. (DSUF ¶ 48; PR ¶ 48.)

On April 15, 2009, Reckitt's Mike Schmidt emailed MonoSol a "Preliminary Strip Forecast for Launch," noting that "this is what we will use to plan for the launch." (DSUF ¶ 49; PR ¶ 49.)

Vince Viviani, MonoSol's production lead, shared the projection with Mr. Schobel and others, explaining that "this is the first real schedule we got from Reckitt." (DSUF ¶ 50; PR ¶ 50.) The April 2009 Reckitt schedule forecasted 7.5 million doses of Suboxone film in 2009, followed by 12.9 million doses for January through June 2010. (DSUF ¶ 51; PR ¶ 51.)

Thereafter, Reckitt started asking MonoSol "to increase its Suboxone film production output through primary packaging to accommodate a monthly run rate of 10-12.5 MM strips starting in early 2010 and beyond"—a 300+% increase in forecasted value (MonoSol's Ex. 19.) MonoSol agreed to build capacity, but indicated that it needed a capital investment in order to "execute as needed to meet the desire Suboxone capacity build." (Id.) MonoSol's then-chief financial officer Keith Kendall explained that Reckitt's increased demands exceeded MonoSol's capacity: "they wanted us to have a manufacturing capacity available to them at a number much higher than we ever have claimed to have for them based on the original agreement. And we didn't have the capital to be able to reflect that change or that increase" (DSUF ¶¶ 53–54; PR ¶ 53–54.) Mr. Kendall remarked that MonoSol was "concerned that, if we could not meet their manufacturing requirements, . . . there was a clause in the agreement that allowed them to take our intellectual property and go put someone else in business making film with our knowhow." (MonoSol's Ex. 3, Dep. of Keith Kendall ("Kendall Dep.") 108:19–109:1.)

As a result of the alleged increase in "capacity commitments" MonoSol began renegotiation of its agreement with Reckitt. (MonoSol's Ex. 1, Schobel Dep. 153:6–154:6.) The November 13, 2009 second amendment to the Commercial Agreement stated:

> [Reckitt] agrees to pay [MonoSol] in advance of Four Million Five Hundred Thousand U.S. Dollars (USD $4,500,000) on the Royalties payable to [MonoSol] . . . upon receiving approval of its new drug application (NDA) for the Products [film] from the FDA. [MonoSol] hereby agrees that RB shall be entitled to receive interest on this advance in the amount of three percent (3%) per annum and that the

> total amount of the advance, plus accumulated interest, shall be credited against the Royalties payable by [Reckitt] to [MonoSol] . . .

(MonoSol's Ex. 21 (emphasis in original).)

During 2008 and 2009, MonoSol and Reckitt met frequently on issues related to development work. (States' Ex. 40.) MonoSol, however, did not actually begin manufacturing saleable production lots of Suboxone film until August 2009. (MonoSol Ex. 34.) In June 2009, MonoSol and Reckitt prepared joint communications to the United States Drug Enforcement Agency justifying the amounts of buprenorphine MonoSol needed for Suboxone film commercialization, indicating "[t]he current forecast has been modeled to assume that there will be no generic entry upon loss of exclusivity (09-Oct-200) and a drive to maximize patient switch from the current tablet formulation to the strip formulation." The communication noted that "[a]ny questions related to the tablet forecast would need to be directed to Reckitt Benckiser Pharmaceuticals." (States' Ex. 41.) On June 17, 2009, Mr. Schobel relayed to MonoSol board member Doug Bratton that Reckitt intended to replace "their entire 150MM/yr tablet franchise with film to stave off generic competition. Original forecast was 20 MM film doses." (States' Ex. 14.) Mr. Schobel did not understand this to mean that Reckitt was withdrawing its tablets from the market. (MonoSol Ex. 28, Schobel Dep. 233:11–17.)

In February 2010, Mr. Schobel reported to the MonoSol board that he was in contact with Reckitt president Shaun Thaxter twice a week and that the MSRx project team was in close contact with the Reckitt commercialization people. (States' Ex. 43.) Mr. Schobel explained that this was not a routine communication pattern with Mr. Thaxter and this more frequent communication was occurring because the NDA had just been approved. (MonoSol Ex. 28, Schobel Dep. 93:3–21.)

MonoSol considered itself a strategic partner with Reckitt relative to the Suboxone film project. (PSUF ¶ 110; DR ¶ 110.) On January 30, 2009, Reckitt expressed disappointment with

MonoSol's "absence of commitment to dates for deliverables." (States' Ex. 47.) In a February 3, 2009 email response from MonoSol to Reckitt, MonoSol stated "[w]e have been a committed partner to [Reckitt] over the last 2 years and rest assured that we have a continued commitment to this project. We have always bent over backwards to meet all the requirements and needs of RB from R&D to commercial. The Suboxone program has grown beyond our expectations and we continue to put more resources to meet the objectives of this program." (Id.)

MonoSol revenues from manufacture and supply of commercial products for the five years from 2010 through 2014 totaled approximately $100 million, which was substantially all derived from the manufacture and sale of Suboxone to Reckitt. (PSUF ¶ 127; DR ¶ 127.)

### C. Reckitt's Withdrawal of Suboxone Tablets and Citizen Petition

On September 18, 2012, Reckitt sent a notice to the FDA that it was discontinuing the manufacture and distribution of Suboxone Tablets. (DSUF ¶ 58; PR ¶ 58.) Nobody from MonoSol was copied on, or otherwise aware of, this notice at the time it was sent. (DSUF ¶¶ 59–60; PR ¶¶ 59–60.) On September 25, 2012, Reckitt issued a press release announcing its decision to withdraw Suboxone tablets. (DSUF ¶ 62; PR ¶ 62.) That same day, Reckitt also filed a Citizen Petition requesting that the FDA refrain from approving any ANDA [Abbreviated New Drug Application for a generic drug] for Suboxone (a) unless the ANDA includes a targeted pediatric exposure program; (b) unless the ANDA has child-resistant unit-dose packaging; and (c) until the FDA determines whether Reckitt withdrew its tablets for safety reasons.[7] (MonoSol Ex. 23.)

Around the same time that Reckitt filed its Citizen Petition and made its public withdrawal announcement, Reckitt's CEO Shaun Thaxter called Mr. Schobel to tell MonoSol that Reckitt had

[7] FDA regulations provide the opportunity for "any interested" person to file a citizen position requesting the FDA "to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.25.

decided to withdraw the tablets and was filing a Citizen Petition. (DSUF ¶ 63; PR ¶ 63.) The parties offer conflicting evidence as to whether MonoSol was involved in discussions related to whether to withdraw the tablets. (Compare Schobel Decl. ¶¶ 18-21 (stating that MonoSol was not involved in any discussions with Reckitt about discontinuing Suboxone Tablets or filing a Citizen Petition regarding safety-issues related to Suboxone tablets); MonoSol Ex. 1, Schobel Dep. 230:14–231:16 (stating that MonoSol "unequivocally" did not participate with Reckitt in filing the Citizens Petition); MonoSol Ex. 2, Schobel 30(b)(6) Dep. 421:13–422:6 (stating that there were no agreements between MonoSol and Reckitt regarding withdrawal of the tablets) with States' Ex. 9 (opinion document from Reckitt's regulatory consultant noting that MonoSol's regulatory consultant suggested withdrawal of tablet and replacement with film); Ex. 10 (opinion document from Reckitt's regulatory consultant noting that "[t]he approach recommended by MonoSol Rx is to replace the current sublingual tablet product with an ODF formulation and then withdraw the tablet product from the market."); Ex. 15 (MonoSol regulatory consultant's notes from August 24, 2011 meeting with Reckitt stating that Reckitt's strategy was focused on "converting 100% of tablets to film").

MonoSol did not participate in any negotiations involving a potential single, shared REMS safety program and did not keep MonoSol informed regarding the status of any such negotiations. [8] (States' Ex. 2, Schobel 30(b)(6) Dep. 425:4–22.) MonoSol also claims that it was not involved in pricing, marketing, or selling Suboxone film or tablets. (MonoSol Ex. 2, Schobel Dep. 420:4–12, 429:6–433:16; MonoSol Ex. 3, Kendall Dep. 32:2–9.) The States cite to evidence reflecting that MonoSol and Reckitt engaged in conversations where plans for rebating patient co-pays was

[8] A REMS or a Risk Evaluation and Mitigation Strategies program is often required by the FDA to ensure that the benefits of a drug or biological product outweigh its risks. The FDA can also require that ANDA sponsors coordinate with the manufacturer of the branded counterpart drug for the purposes of creating a Single Shared REMS program ("SSRS").

discussed in mid-2010. (States' Ex. 17; States' Ex. 18; States' Ex. 20.) As of September 1, 2010, MonoSol representatives were aware of Reckitt's public statements that film was safer than tablets in terms of pediatric exposure. (States' Ex. 1, Schobel 30(b(6) Dep. 155:17–157:19.)

## II. STANDARD OF REVIEW

Federal Rule of Civil Procedure 56 states, in pertinent part:

> A party may move for summary judgment, identifying each claim or defense—or the part of each claim or defense—on which summary judgment is sought. The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. The court should state on the record the reasons for granting or denying the motion.

Fed. R. Civ. P. 56(a). "Through summary adjudication, the court may dispose of those claims that do not present a 'genuine dispute as to any material fact' and for which a jury trial would be an empty and unnecessary formality." Capitol Presort Servs., LLC v. XL Health Corp., 175 F. Supp. 3d 430, 433 (M.D. Pa. 2016). A factual dispute is "material" if it might affect the outcome of the suit under the applicable law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). An issue is "genuine" only if there is a sufficient evidentiary basis that would allow a reasonable fact-finder to return a verdict for the non-moving party. Id.

The initial burden is on the moving party to adduce evidence illustrating a lack of genuine, triable issues. Hugh v. Butler Cnty. Family YMCA, 418 F.3d 265, 267 (3d Cir. 2005). Once the moving party satisfies its burden, the non-moving party must, in rebuttal, present sufficient evidence of a genuine issue, in rebuttal. Santini v. Fuentes, 795 F.3d 410, 416 (3d Cir. 2015). The court must then resolve all doubts as to the existence of a genuine issue of material fact in favor of the non-moving party. Saldana v. Kmart Corp, 260 F.3d 228, 232 (3d Cir. 2001). Summary judgment is appropriate if the non-moving party provides merely colorable, conclusory or speculative evidence. Anderson, 477 U.S. at 249. There must be more than a scintilla of evidence supporting the non-

moving party and more than some metaphysical doubt as to the material facts. Id. at 252. Unsubstantiated arguments made in briefs are not considered evidence of asserted facts. Versarge v. Twp. of Clinton, 984 F.2d 1359, 1370 (3d Cir. 1993). Moreover, "a party resisting a [Rule 56] motion cannot expect to rely merely upon bare assertions, conclusory allegations or suspicions." Gans v. Mundy, 762 F.2d 338, 241 (3d Cir. 1985) (citing Ness v. Marshall, 660 F.2d 517, 519 (3d Cir. 1981)).

## III. DISCUSSION

### A. The Law Regarding Antitrust Conspiracies

"To prevail on a section 1 claim or a section 2 conspiracy claim, a plaintiff must establish the existence of an agreement, sometimes also referred to as a 'conspiracy' or 'concerted action.'" W. Penn Allegheny Health System, Inc. v. UPMC, 627 F.3d 85, 99 (3d Cir. 2010) (quotations omitted). "An agreement exists when there is a unity of purpose, a common design and understanding, a meeting of the minds, or a conscious commitment to a common scheme." Id. (citing Copperweld Corp. v. Indep. Tube Corp., 467 U.S. 752, 771 (1984)) (further citations omitted). "'Unilateral activity by a defendant, no matter the motivation, cannot give rise to a section 1 violation.'" InterVest, Inc. v. Bloomberg, L.P., 340 F.3d 144, 159 (3d Cir. 2003). Rather, for liability under § 1 to exist, there must be a "unity of purpose or a common design and understanding or a meeting of the minds in an unlawful arrangement." Havens v. Mobex Network Servs., LLC, 820 F.3d 80, 91 (3d Cir. 2016) (quotation omitted).

A plaintiff is not required to show that a defendant "knew of or participated in every transaction in furtherance of or related to the alleged conspiracy." In re Railway Indus. Employee No-Poach Antitrust Litig., 395 F. Supp. 3d 464, 494 (W.D. Pa. 2019) (quotation omitted). On the other hand, mere proof that a defendant *knew* about a conspiracy, without more, is insufficient to establish an alleged conspiracy. Id. Rather, a plaintiff must show that the defendant (1) had

knowledge of the agreement, and (2) intended to join the agreement. "'[A] party progresses from mere knowledge of an endeavor to intent to join it when there is informed and interested cooperation, stimulation, instigation. And there is also a "stake in the venture" which, even if it may not be essential, is not irrelevant to the question of conspiracy.'" In re Vitamins Antitrust Litig., 320 F. Supp. 2d 1, 16 (D.D.C. 2004) (quoting Direct Sales Co. v. United States, 319 U.S. 703, 713 (1943)). "The intent that must be shown in a conspiracy case is the intent to advance the unlawful purpose of the conspiracy." Id.; see also Pa. Dental Ass'n v. Med. Serv. Ass'n of Pa., 745 F.2d 248, 260–61 (3d Cir. 1984) ("[A] mere intention to prevail over rivals or improve market position is insufficient. Even an intent to perform acts that can be objectively viewed as tending toward the acquisition of monopoly power is insufficient, unless it also appears that the acts were not 'predominately motivated by legitimate business aims.'").

To establish an agreement, a plaintiff may rely on direct or circumstantial evidence, or a combination of the two. W. Penn, 627 F.3d at 99. Direct evidence must be evidence that is explicit and requires no inferences to establish the proposition or conclusion being asserted. In re Baby Food Antitrust Litig., 166. F.3d 112, 118 (3d Cir. 1999). Where a plaintiff lacks direct evidence, it may rely solely on circumstantial evidence and the reasonable inferences that may be drawn therefrom. InterVest, 240 F.3d at 159. A court then "must ascertain whether the plaintiffs have presented 'evidence that is sufficiently unambiguous' showing that the defendants conspired." In re Baby Food, 166 F.3d at 124 (quoting Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 597 (1986)).

Although the motion for summary judgment standard in antitrust cases is generally no different from the standard in other cases, there is "an important distinction" in antitrust cases. In re Chocolate Confectionary Antitrust Litigation, 801 F.3d 383, 396 (3d Cir. 2015). "[A]ntitrust law limits the range of permissible inferences from ambiguous evidence in a § 1 case." Matsushita, 475

U.S. at 588. "[C]onduct as consistent with permissible competition as with illegal conspiracy does not, standing alone, support an inference of antitrust conspiracy." Id.; see also Chocolate Confectionary, 801 F.3d at 396. Therefore, unless the plaintiff "present[s] evidence 'that tends to exclude the possibility' that the alleged conspirators acted independently," summary judgment is appropriate. Matsushita, 475 U.S. at 588 (quoting Monsanto Co. v. Spray-Rite Serv. Corp., 465 U.S. 752, 764 (1984). The purpose of this standard is to avoid mistaken inferences that could impose liability for lawful conduct and, consequently, "chill the very conduct the antitrust laws are designed to protect." Id. at 594; accord In re Flat Glass Antitrust Litig., 385 F.3d 350, 357 (3d Cir. 2004) ("This higher threshold is imposed in antitrust cases to avoid deterring innocent conduct that reflects enhanced, rather than restrained, competition.")

"Under Matsushita, the range of acceptable inferences that may be drawn from ambiguous or circumstantial evidence "var[ies] with the plausibility of the plaintiffs' theory and the dangers associated with such inferences." Chocolate Confectionary, 801 F.3d at 396 (some quotations omitted). "If the plaintiff's theory 'makes no economic sense' and if drawing inferences in its favor would deter procompetitive conduct, the plaintiff must produce 'more persuasive evidence' to support its claim." Id. "Importantly, even when armed with a plausible economic theory, a plaintiff relying on ambiguous evidence alone cannot raise a reasonable inference of a conspiracy sufficient to survive summary judgment." Id. (citing Matsushita, 475 U.S. at 597 n.21; Rossi v. Standard Roofing, Inc., 156 F.3d 452, 466 (3d Cir. 1998)). By the same token, "defendants are [not] entitled to summary judgment merely by showing that there is a plausible explanation for their conduct; rather the focus must remain on the evidence proffered by the plaintiff and whether that evidence tends to exclude the possibility that the defendants were acting independently." Rossi, 156 F.3d at 467 (internal quotation marks and brackets omitted).

The United States Court of Appeals for the Third Circuit requires that plaintiffs relying on circumstantial evidence of an agreement show that certain "plus factors"—*i.e.*, something more than mere parallel behavior—also exist. In re Flat Glass, 385 F.3d at 360 (citing Baby Food, 166 F.3d at 122; Petruzzi's IGA v. Darling–Delaware, 998 F.2d 1224, 1230 (3d Cir. 1993)). "Existence of these plus factors tends to ensure that courts punish 'concerted action'—an actual agreement—instead of the 'unilateral, independent conduct of competitors.'" Id. (citing Baby Food, 166 F.3d at 122). Although there is no finite set of plus factors and no exhaustive list exists, the Third Circuit has explained:

> For circumstantial evidence of an agreement, then, a plaintiff must allege both parallel conduct and something "more," which we have sometimes called a "plus factor." This "more" could include evidence (1) "that the defendant had a motive to enter into a . . . conspiracy," (2) "that the defendant acted contrary to its interests," or (3) "implying a traditional conspiracy."

Lifewatch Servs., Inc. v. Highmark, Inc., 902 F.3d 323, 333 (3d Cir. 2018) (internal citations omitted).

**B. Whether MonoSol Conspired With Reckitt to Restrain Trade**

As set forth in more detail in my August 22, 2022 Memorandum Opinion on Reckitt's Motion for Summary Judgment, this case involves allegations of a multi-faceted antitrust scheme. Plaintiffs' theory is premised on a long chronology of events that centers on the fact that, in 2009, Reckitt was facing a "patent cliff," *i.e.*, the expiration of orphan drug exclusivity on Suboxone tablets. According to Plaintiff, prior to the expiration of this exclusivity period, and prior to the entry of generics, Reckitt, in partnership with MonoSol, introduced a product re-formulation in the form of Suboxone film—which was not AB-rated with tablets—and then withdrew the tablet, effectively forcing patients that depended on Suboxone to switch to the film version. The Plaintiffs' antitrust theory, however, does not end there. Plaintiffs further allege that Reckitt then allegedly

disseminated false safety concerns regarding Suboxone tablets, made irrational price increases on tablets, and delayed generic entry by filing a sham Citizen Petition and not cooperating in the shared REMS process.

Throughout this litigation, all Plaintiffs, including the States, have continually urged that I consider this alleged antitrust scheme as whole, regardless of whether the individual parts of the scheme are lawful. (See States' Opp'n Reckitt's Mot. Summ. J., ECF No. 732 p. 5 ("To insist that each discrete act must itself be illegal in order to be part of an overall product hop theory would be to render product hop liability completely meaningless; by their nature, those theories contemplate more than one isolated act by a defendant. It is their effect, taken together, which gives rise to antitrust liability.").) Yet, as it pertains to MonoSol, the States point to no evidence that implicates MonoSol in the entirety of the scheme. Rather, the States' theory is only that MonoSol (a) conspired with Reckitt to introduce the film onto the market and withdraw the tablet, (b) was tacitly complicit in Reckitt's marketing campaign, raising of tablet prices, and filing of a Citizens Petition, and (c) maintained a financial interest in film's success on the market. In support of this theory and in opposition to summary judgment, the States cite to the following evidence:

- MonoSol promoted itself to Reckitt and other potential investors that its film product allowed brand drug manufacturers to extend product life cycles and to protect against generic encroachment.

- MonoSol recognized that enabling Reckitt to prevent generic substitution of its Suboxone film might not be enough for Reckitt to maintain its monopoly. As such, in December 2006, when MonoSol met with Reckitt, the companies agreed that the goal was to withdraw the NDA for tablets to replace the market with Suboxone film. This was different than Reckitt's previous idea to "replace" tablets with film. As MonoSol president Mark Schobel testified, "[w]ithdrawing something is removing it. Replacing is . . when something of superior value causes a conversion of choices, a different choice." (States Ex. 1, Schobel 30(b)(6) Dep., 447:20–449:16.) The contemporaneous business records of Reckitt's regulatory consultant, Pharma Directions, and Reckitt itself, could support that the idea to withdraw the Suboxone

tablet originated with MonoSol.[9] In any event, MonoSol was a party to discussions with Reckitt about the scheme to replace and withdraw the tablet NDA.

- MonoSol committed to participating in the plan to fully replace Suboxone tablets "to stave off generic competition" by June 2009. MonoSol worked with Reckitt to correspond with the Drug Enforcement Agency.

- It was originally MonoSol's suggestion for Reckitt to replace tablets with film and withdraw the tablets' NDA. As early as 2008, MonoSol confirmed that it had adequate capacity to produce enough strips to fulfill Reckitt's eventual forecast to fully replace tablets with film (150 million strips). The Commercial Exploitation Agreement contained no specific production requirements.

- MonoSol had incentive to ensure Reckitt's monopoly. MonoSol was paid not only on a per-strip basis, but was also given royalties to share in Reckitt's profits. Moreover, MonoSol negotiated its own costs with Reckitt to ensure profitability.

- The Development Agreement and the Commercial Exploitation jointly represented the "cornerstone" of the Defendants' overarching scheme to extend Reckitt's monopoly.

The question is whether this evidence, viewed in favor of the States, is sufficient to create a genuine issue of fact as to whether MonoSol had a conscious commitment to this overall scheme such that MonoSol can be said to have conspired with Reckitt. For the following reasons, I find that this evidence is not sufficient to defeat summary judgment:

**First**, MonoSol's (a) promotion of its products as protection against generic encroachment and (b) production of a drug formulation that is not AB-rated to other versions, while detrimental to competitors, are not prohibited activities under antitrust laws. "[T]o be condemned as exclusionary, a monopolist's act must have an 'anticompetitive effect.' That is, it must harm the competitive *process* and thereby harm consumers. In contrast, harm to one or more *competitors* will not suffice." U.S. v. Microsoft Corp., 253 F.3d 34, 58 (D.C. Cir. 2001) (emphasis in original); Broadcomm Corp. v. Qualcomm Inc., 501 F.3d 297, 308 (3d Cir. 2007) ("Conduct that merely harms competitors . . .

[9] MonoSol contends that this evidence is hearsay that may not be considered on a motion for summary judgment. Because I find that MonoSol is entitled to summary judgment even if I consider this evidence, I decline to resolve the hearsay objection.

while not harming the competitive process itself is not anticompetitive."). To that end, antitrust law recognizes that "[i]n a competitive market, firms routinely innovate in the hope of appealing to consumers, sometimes in the process making their products incompatible with those of rivals; the imposition of liability when a monopolist does the same thing will inevitably deter a certain amount of innovation." Microsoft, 253 F.3d at 65. Repeatedly, courts have rejected allegations that a company's development of a product that is incompatible with existing products is unlawfully anticompetitive absent some associated conduct which constitutes an exclusionary means of attempting to monopolize the market, rather than aggressive competition on the merits. See, e.g., Mylan Pharms., Inc. v. Warner Chilcott Public Ltd. Co., 838 F.3d 421, 440 (3d Cir. 2016); Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP, 592 F.3d 991, 999 (9th Cir. 2010).

Given these standards, MonoSol's development and marketing of film as a means by which brand pharmaceutical manufacturers could extend the life of their patents and protect against generic encroachment, standing alone, does not constitute anticompetitive conduct violative of the antitrust laws. In turn, MonoSol and Reckitt's agreement to develop a film form of Suboxone that would not be AB-rated to the tablet form, and thus not automatically substitutable with generic tablets, is not, without more, a lawful business contract. To hold otherwise would suggest that a company such as MonoSol, whose sole purpose is the development and marketing of film, could not pursue its business goals without violating antitrust laws.

**Second**, the States' allegation that MonoSol suggested the "hard switch"—*i.e.*, that Reckitt withdraw the tablet from the market and sell only brand Suboxone film—also does not create a genuine issue as to whether MonoSol conspired to participate in an unlawful scheme. The States have pointed to evidence that the idea of tablet withdrawal was initiated by MonoSol. Monosol disputes this proposition and presents evidence that the withdrawal of tablets was contrary to its financial interests, that Reckitt contemplated withdrawing its Suboxone tablet before it ever met

with MonoSol to discuss film, that the withdrawal idea originated with Reckitt, and that MonoSol did not learn of the actual withdrawal until after Reckitt advised the FDA of its decision. In the face of this competing evidence, I cannot—under Federal Rule of Civil Procedure 56 standards—make a credibility determination. Rather, considering all evidence in the light most favorable to the States, I find that conflicting facts exist as to precisely who initiated the suggestion for withdrawal of tablets. Nonetheless, resolution of that issue of fact is not material to my ruling on summary judgment.

Even assuming that MonoSol originally suggested the introduction of film and the withdrawal of the tablet, and the parties discussed that idea, none of that evidence creates a reasonable inference that MonoSol and Reckitt reached an *agreement* or conscious commitment that Reckitt would actually withdraw tablets in furtherance of a common, multi-faceted scheme. Indeed, the undisputed evidence does not "tend to exclude the possibility" that Reckitt "acted independently" when withdrawing the tablet:

- In April 2006, MonoSol met with Reckitt to discuss buprenorphine products. (Schobel Decl. ¶ 12.) According to the States' evidence, at that meeting, MonoSol *suggested* replacing the current sublingual tablet product with film and then withdrawing the tablet product from the market. (States' Exs. 9, 10.) There is no evidence that *any* agreement was reached between MonoSol and Reckitt, and indeed, Reckitt had not committed to working with MonoSol at this time. (MonoSol Ex. 9 (MonoSol email outlining strategic points to be used to communicate benefits of film technology to Reckitt's CEO).)

- On December 11, 2006, MonoSol executed the Development Agreement with Reckitt. That Agreement provided only that MonoSol would develop and test a film dose form for Suboxone. Nothing in that agreement discussed withdrawal of tablets.

- An internal exchange of Reckitt emails in January 2007 reflects that Reckitt still had not decided whether or not it was going to proceed forward with MonoSol or use a rival company known as "Adipate." Reckitt was still considering what the barriers would be to removing tablets from the market and replacing them with the MonoSol product. There is no evidence that these emails were shared with MonoSol. (States' Ex. 8.)

- In February of 2007, Reckitt engaged PharmaDirections for an "urgent" regulatory evaluation of proposed development plans with MonoSol. PharmaDirections evaluated advantages and disadvantages of withdrawing the tablet versus leaving the tablet on the

market, again establishing that, at this time, Reckitt had not adopted any particular course of action. (States' Ex. 9.)

- On February 16, 2007, an internal Reckitt email stated that Reckitt was assessing a marketing switch strategy in which it would withdraw tablets by showing the safety benefits of the film over the tablet. (States' Ex. 11.) This email was not shared with MonoSol, and there is no indication that MonoSol was part of this assessment.

- On February 22, 2007, several individuals from Reckitt joined representatives of MonoSol, as well as MonoSol's regulatory consultant Robert Pollock, on a conference call. During that call, Mr. Pollack took handwritten notes, including "WDSL tab to delay," which meant "withdraw sublingual tablet to delay." (DSUF ¶¶ 22–23; PR ¶¶ 22–23.) Mr. Pollock did not recall whether he or someone else made that statement or even if the subject of withdrawal coming up in the phone call. (MonoSol Ex. 4, Pollack Dep. 108:6–109:21.) But Mr. Pollock testified that, to his knowledge, he was never asked by MonoSol to develop a withdrawal strategy. (Id. at 268:10–269:3.)

- On the same day, Reckitt executives had an internal email discussion and noted that "Suboxone/Subutex Monosol formulation under the current path provides no generic protection. The NDA for Suboxone cannot be pulled as the generic will still have the right of reference to the data in the NDA. Therefore, not the protection we were led to believe from Robert Pollock and MonoSol when they visited us in Dec. 06." (MonoSol Ex. 13.) Although MonoSol is mentioned in these emails, it was not a party to this discussion.

- In an internal Reckitt email from March 2007, a Reckitt representative stated that "the current plan calls for introducing the film in June 2009, transitioning pts from the [tablets] to the film, and then withdrawing the [tablets] altogether prior to October, 2009." (States' Ex. 12.) Again, MonoSol was not a party to this discussion.

- In an August 30, 2007 email to members of both Reckitt and MonoSol, Reckitt thanked everyone for their hard work on submitting the Investigational New Drug application for Suboxone film. (States' Ex. 33.) Nothing in the email discussed withdrawal of tablets.

- On August 15, 2008, Reckitt and MonoSol entered into the Supply Agreement, which only required MonoSol to manufacture and supply film in order to meet Reckitt's capacity demands. This agreement did not mention any responsibilities designated to MonoSol regarding tablet withdrawal, marketing, or pricing. (MonoSol Ex. 14.)

- On August 22, 2008, MonoSol's Mark Schobel asked its regulatory consultant Robert Pollock, "[if] our customer, [Reckitt], withdraws their sublingual suboxone tablets from the market and change the code for the Suboxone tablets in the [National Drug Data File] to 'obsolete' can pharmacies still fill prescriptions for a generic sublingual tablet." Mr. Pollock responded that "if the [tablet] has not been withdrawn for safety or efficacy reasons, Generics can be approved for the SL product (it will not be AB rated since it is a pharmaceutical alternative)." MonoSol's Keith Kendall responded, "That is not helpful." (States' Ex. 35.) Mr. Kendall explained that because he had never been in the pharmaceutical industry before and did not understand the "gobbledy-gook," the answer was not helpful. (MonoSol Ex. 29,

Kendall Dep. 212:1–15.) This exchange does not establish or allow any inference of MonoSol's active involvement in tablet withdrawal.

- MonoSol was involved in meetings with Reckitt and the FDA to listen and provide answers to questions that the FDA had about the dosage form. (States Ex. 7, Schobel 30(b)(6) Dep. 123:21–125:6.)) None of these meetings had anything to do with tablet withdrawal.

- It was not until June 2009 that MonoSol's Schobel first relayed to MonoSol board member Doug Bratton that Reckitt has indicated that it will be "replacing their entire 150 MM/year tablet franchise with film to stave off generic competition." (States' Ex. 14.) Mr. Schobel noted that the original forecast was for only 20 million Suboxone film strips. (Id.) In order to meet these increased capacity commitments, MonoSol renegotiated its Supply Agreement. But the renegotiated Supply Agreement did not include MonoSol's involvement with tablet withdrawal.

- In August 2011, MonoSol was aware that "Reckitt's strategy [was] still focused on converting 100% tablets to film" and of Reckitt's "position of moving all Suboxone to film for safety and reduced pediatric exposure." (States' Ex. 15.) This email only suggests MonoSol's awareness of potential tablet withdrawal and does not suggest there was any joint strategy between the companies.

- On September 25, 2012, Reckitt issued a press release announcing its decision to withdraw Suboxone Tablets. That same day, Reckitt's CEO Shaun Thaxter called Mr. Schobel to tell MonoSol that Reckitt had decided to withdraw the tablets and was filing a Citizen Petition. (DSUF ¶ 63; PR ¶ 63.) Mr. Schobel then forwarded that press release to MonoSol's board members with the notation, "always thought that might be the case." (States' Ex. 16.) The sole inference from these events is that this was not a joint plan but merely one that was suspected by MonoSol.

While the foregoing evidence indicates that MonoSol may have suggested early on that withdrawal of the tablet was a potential strategy to protect against generic incursion and also may have suspected that Reckitt would take that route, mere suggestion or awareness of that strategy is insufficient to establish an antitrust conspiracy. See In re Baby Food, 166 F.3d 112, 133 (3d Cir. 1999) (acknowledging that "courts generally reject conspiracy claims that 'seek to infer an agreement from . . . communications despite a lack of independent evidence tending to show an agreement in the face of uncontradicted testimony that only information exchanges took place.'"). Instead, this evidence reflects that Reckitt and MonoSol never had "a unity of purpose, a common design and understanding, a meeting of the minds, or a conscious commitment to a common

scheme." W. Penn Allegheny, 627 F.3d at 99. By all accounts, other than the "suggestion" of withdrawing tablets, MonoSol took no action to help Reckitt effectuate that strategy. In fact, MonoSol had no ability to cause the withdrawal of Suboxone tablets from the market, could not have prevented Reckitt from withdrawing the tablets, and was not even aware of the final withdrawal decision until after it was made. The States have presented no direct or circumstantial evidence that would allow any reasonable jury to find that such a conspiracy existed.[10]

**Third**, the States have produced no evidence that allows a reasonable inference that MonoSol agreed to any other portion of the alleged antitrust conspiracy beyond suggesting and being aware of the withdrawal of the tablets. These additional anticompetitive actions include the

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[10] Even assuming *arguendo* that MonoSol did reach an agreement with Reckitt regarding tablet withdrawal, it is not clear that mere introduction of a new product combined with withdrawal of the prior product, standing alone, could be the basis of an unlawful antitrust conspiracy. It is well settled that "neither product withdrawal nor product improvement alone is anticompetitive." New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638, 653–54 (2d Cir. 2015) ("Namenda"). The States rely on the Second Circuit decision in Namenda, wherein the court found that a drug manufacturer's hard switch—*i.e.*, the combination of withdrawing their originally branded drug and introducing a new, non-AB-rated version of that drug—forced patients who depended on that therapy to switch to the new version of the drug "and would likely impede generic competition by precluding generic substitution through state drug substitution laws." Id. at 654.

Since Namenda, however, courts have indicated that some conduct beyond the hard switch is necessary to prove unlawful, anticompetitive conduct. See, e.g., In re Loestrin 24 Fe Antitrust Litigation, 433 F. Supp. 3d 274, 330–31 (D.R.I. 2019) ( "[T]o sustain a claim, a hard switch must be accompanied by additional evidence that [the defendants'] anticompetitive conduct coerced consumers to switch from [one product to another] . . . Thus, Plaintiffs must identify evidence of conduct beyond the hard switch that could support a jury finding that [a defendant] employed anticompetitive conduct to coerce consumers to switch from [one product to another]."); Mylan Pharms Inc. v. Warner Chilcott Public Ltd., 838 F.3d 421, 440 (3d Cir. 2016) ("Doryx") (affirming that the conduct evidenced a lawful soft switch, but also appreciating that "certain insignificant design or formula changes, combined with other coercive conduct, could present a closer call with respect to establishing liability").

Absent some showing of MonoSol's participation or agreement to the entirety of the alleged antitrust, it is not clear, as a matter of law, whether simple participation in the hard switch—*i.e.*, the introduction of film and the withdrawal of tablets—would be sufficient to hold MonoSol liable for an antitrust conspiracy. Nonetheless, as I find that there was no meeting of the minds even as to withdrawal, I need not resolve this issue.

increase in Suboxone tablet pricing, the allegedly false safety marketing campaign, the Citizen Petition, and the delay in the shared REMS process.[11] For example, the States attempt to implicate MonoSol in the pricing allegations by arguing that, in mid-2010 and mid-2011, Reckitt shared with MonoSol information regarding rebating patient co-pays, and Reckitt's coupon and copay program. (States' Exs. 18, 19.) The States also contend that MonoSol "took note" of CVS' July 2013 removal of Suboxone from its list of covered medications, observing to a third party in response to a public news article, that "now it becomes a pricing game and Reckitt could retain scripts and patients by continuing to coupon appropriately." (PSUF ¶ 15; States' Ex. 21.) The States further argue that "MonoSol was also aware of and supported Reckitt's unsubstantiated public safety marketing statements." (PSUF ¶ 116.) Specifically, after seeing an article about an interview with Reckitt President Shaun Thaxter, who discussed safety benefits of Suboxone film, a MonoSol board member observed that it was a "[g]reat interview!" (States' Ex. 22.)

The States' evidence, however, goes no further. Mere awareness of and private support for actions by an alleged monopolist do not establish that there has been a meeting of the minds or conscious commitment to a common goal. To the contrary, the sole rational inference from this evidence is that MonoSol had no part in either the pricing of film/tablets or in the marketing

[11] The States cite to my decision on MonoSol's Motion to Dismiss in this case, wherein I found that the allegations of the Amended Complaint permitted the plausible inference that MonoSol and Reckitt engaged in concerted action with MonoSol on a significant portion of the alleged product hop scheme. In re Suboxone, 16-cv-5073, 2017 WL 4910673, at *11 (E.D. Pa. Oct. 30, 2017). For purposes of a motion to dismiss, I found such allegations, taken as true, were sufficient to state a plausible claim that the two companies had a meeting of the minds to engage in a joint scheme that would allow Reckitt to monopolize the relevant market.

However, the evidence produced by the States after the pleading stage—even taken in the light most favorable to the States—has not borne out the theory that such a meeting of the minds occurred. Indeed, the States have conceded that MonoSol did not participate in the disparagement of tablets, pricing of tablets, the Citizen Petition, or the alleged REMS delay. As completely different standards apply, the denial of MonoSol's motion to dismiss does not dictate the outcome of MonoSol's motion for summary judgment.

campaign regarding film and tablets. Rather, it was an interested observer of actions being taken unilaterally by Reckitt. Nothing in the evidence of record indicates that MonoSol had any input or control over pricing or marketing.

**Fourth**, the States posit that the Development and Supply Agreements were the foundation of the common scheme because they provided MonoSol the economic incentive to develop Suboxone film and obtain the necessary patents and FDA approvals. The States point out that MonoSol was not paid strictly on a per-strip basis but also received royalties to share in Reckitt's profits, *i.e.*, the more film Reckitt sold, the more profits for MonoSol. The States note that MonoSol represented that it "always bent over backwards to meet all the requirements and needs of RB from R&D to commercial." (States' Ex. 47.)

Again, "the Sherman Act 'directs itself not against conduct which is competitive, even severely so, but against conduct which unfairly tends to destroy competition itself.'" Doryx, 838 F.3d at 438 (quoting Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 458 (1993)). The Development and Supply Agreements were, on their face, lawful and procompetitive contracts between Reckitt and MonoSol. Developing a new product and getting paid for it, including a royalty, is fully consistent with legitimate conduct and does not create an inference of anticompetitive behavior. Nothing in the Development and Supply Agreements suggests a conspiracy to achieve any unlawful objective in restraint of trade. Likewise, MonoSol's representation that it "bent over backwards" to meet its contractual obligations—a statement made in response to Reckitt's expression of disappointment with MonoSol's work—does not suggest nefarious activity. The *possibility* that Reckitt used these contracts as a springboard for a larger antitrust scheme is insufficient to implicate MonoSol in an antitrust conspiracy.

**Fifth**, the States have failed to produce any evidence regarding MonoSol's involvement with the Citizen Petition or the REMS process. As to the Citizen Petition, the States' sole evidence is

that MonoSol and Reckitt had worked together on at least one other unrelated Citizen Petition, and, on the day the 2012 Citizen Petition regarding Suboxone tablets was filed, Mr. Schobel forwarded a press release to the MonoSol board with the note "always thought that might be the case" and "no email responses please but happy to take calls." The States then make the leap that "[t]his evidence supports a reasonable inference that MonoSol participated in the activities alleged. (States' Opp'n Summ J. 22.) Acknowledgement of the Citizen Petition alone, however, is not sufficient evidence to speculate that MonoSol agreed to and participated in the filing of that Citizen Petition with a common purpose of blocking generic entry.

**Finally**, in citing to the following evidence, the States attempt to create an inference of a conspiracy by calling attention to language used by MonoSol that it was a "strategic partner" as opposed to just a contract manufacturer:

- In 2008, MonoSol's financial model was, and continues to be "Partner Driven And Focused" based on "Revenue Share vs. Contract Manufacturer." (States' Ex. 39.)
- In a July 2009 email from Schobel to Shaun Thaxter of Reckitt regarding the renegotiation of the Supply Agreement, Mr. Schobel represented that MonoSol "has and always will be a good partner and is willing and intends to do all that it can to contribute to a successful launch and a long and vibrant product life cycle for the Suboxone® Film. We continue to work with your team to plan and execute that launch and provide the subsequent on-going supply and IP protection for the product within our current capabilities." (States' Ex. 42.)
- In a 2010 speech to prospective investors, Mr. Schobel stated that MonoSol is "not a contract manufacturer but a technology Partner that shares in the value created by our film technology." (States' Ex. 44.)

The use of the word "partner"—oftentimes in connection with marketing presentations to others—does not allow for a reasonable inference that MonoSol was Reckitt's co-conspirator in the alleged antitrust scheme. Companies often choose to present themselves as existing for more than just a mere profit-making purpose. As Mr. Schobel cogently explained, "[w]e want to be good partners to deliver to our customers the things that they ask for. We are separate corporate entities and there is no entanglement as the term partner financially or otherwise can be construed."

(MonoSol Ex. 27, Schobel 30(b)(6) Dep. 149:9–150:12.) Nothing in these statements was untrue or otherwise could be deemed to advance the alleged monopoly scheme in any way.

Overall, "[k]knowledge alone is not sufficient to prove that any particular [d]efendant intended to join [a] conspiracy." In re Vitamins Antitrust Litig., 320 F. Supp. 2d 1, 16 (D.D.C. 2004). "The intent that must be shown in a conspiracy case is the intent to advance the unlawful purpose of the conspiracy." Id. As the Third Circuit has already recognized, the antitrust theory in this matter is not premised on solely one action; rather the States allege "that the totality of [Reckitt's] actions, such as raising prices, withdrawing tablets from the market, providing rebates only for film, disparaging the safety of tablets, and delaying the generics' entry by filing a citizen petition and not cooperating in the REMS process, suppressed generic competition and thus violated the antitrust laws." In re Suboxone, 967 F.3d 264, 270 (3d Cir. 2020). It is the combination of this independently lawful conduct that creates an anticompetitive effect and is actionable under antitrust law. In re Keurig Green Mtn. Single-Serve Coffee Antitrust Litig., 383 F. Supp. 3d 187, 230 (E.D.N.Y. 2019). "Courts have the added responsibility in antitrust conspiracy cases of assuring that underlying lawful conduct is not brought within the prohibitive reach of the law, even inadvertently; they must be careful to condemn only conduct—that is, the agreement—that Congress intended to fall within the reach of the antitrust laws." Coleman v. Cannon Oil Co., 849 F. Supp. 1458, 1465 (M.D. Ala. 1993).

Considered as whole, the evidence here could not lead a rational trier of fact to find that MonoSol intended to be part of a conspiracy to restrain trade or a conspiracy to monopolize. Undisputedly, MonoSol marketed its product to Reckitt on the basis that it would help protect the Suboxone product against generic incursion because film is not AB-rated to tablets. Taking the facts in the light most favorable to the States, there is a reasonable inference that MonoSol suggested to Reckitt that it withdraw the Suboxone tablet from the market and replace it with Suboxone film.

But the evidence of MonoSol's agreement with Reckitt stops there; it does not tend to exclude the possibility that Reckitt acted independently as to the remainder of the alleged scheme. The States have presented no evidence that Reckitt and MonoSol ever reached any agreement, meeting of the minds, or conscious commitment to a common scheme as to the actual withdrawal of tablets, the pricing of tablets or film, the safety marketing campaign, the Citizen Petition, or the REMS process. At best, MonoSol worked diligently to do precisely what it contractually agreed to do: produce Suboxone film sufficient to meet Reckitt's needs in exchange for a per-strip charge and a royalty share of the profits. Antitrust laws do not prohibit agreement to engage in such a lawful endeavor.

Accordingly, I will grant summary judgment in favor of MonoSol and dismiss all claims against it.

An appropriate order follows.